DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL - 8 1997

Re: ESTROSTEP®
Docket No. 97E-0045

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
U.S. Patent and Trademark Office
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Mr. Kunin:

This is in regard to the application for patent term extension for U.S. Patent No. 4,962,098 filed by Warner-Lambert Company under 35 U.S.C. § 156. The human drug product claimed by the patent is ESTROSTEP® (ethinyl estradiol, norethindrone acetate), which was assigned New Drug Application (NDA) No. 20-130.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). However, our records also indicate that it **does not** represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp. 1224 (E.D. Va. 1989), aff'd, 894 F. 2d 392 (Fed. Cir. 1990). For example, LOESTRIN, manufactured by Parke Davis, contains both of the same active ingredients, ethinyl estradiol and norethindrone acetate (see attachment). In addition, both active ingredients have been approved in other products separately. For example, ESTINYL, manfactured by Schering, contains ethinyl estradiol, and AYGESTIN (Wyeth Ayerst) and NORLUTATE (Parke Davis), both contain norethindrone acetate (see attachment).

The NDA was approved on October 9, 1996, which makes the submission of the patent term extension application on November 21, 1996, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.